Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

四环医药
SihuanPharm

Sihuan Pharmaceutical Holdings Group Ltd.

四環醫藥控股集團有限公司

(incorporated in Bermuda with limited liability)

(Stock Code: 0460)

VOLUNTARY ANNOUNCEMENT
NG-350A GRANTED FAST TRACK DESIGNATION BY THE U.S. FDA

The board of directors (the "**Board**") of Sihuan Pharmaceutical Holdings Group Ltd. (the "**Company**" or "**Sihuan Pharmaceutical**", together with its subsidiaries, the "**Group**") is pleased to announce that NG-350A, a product of Xuanzhu Biopharmaceutical Co., Ltd. ("**Xuanzhu Biopharm**"), a non wholly-owned subsidiary of Sihuan Pharmaceutical, licensed from Akamis Bio Ltd. ("**Akamis**"), a clinical-stage oncology company, was granted Fast Track designation by the U.S. Food and Drug Administration ("**FDA**") for the treatment of mismatch repair-proficient (pMMR) locally advanced rectal cancer (LARC). Xuanzhu Biopharm holds exclusive rights to develop, produce and commercialize NG-350A in Greater China. For details of the license agreement with Akamis and NG-350A, see "Business – Our License and Asset Acquisition Arrangements – Our In-licensing and Asset Acquisition Agreements – Agreement with Akamis to In-license an Oncolytic Viral Vector Asset" in the prospectus of Xuanzhu Biopharm dated 6 October 2025.

ABOUT FAST TRACK DESIGNATION

FDA Fast Track designation is a method for expediting the development and approval of potential drugs. Drugs granted Fast Track designation are intended to treat serious conditions and address unmet medical needs. They may be the first treatment for a specific condition, offer significant clinical advantages over existing therapies, or enhance safety for existing therapies.

ABOUT NG-350A

NG-350A is a clinical-stage, intravenously delivered T-SIGn® therapeutic designed to drive intratumoral expression of a CD40 agonist monoclonal antibody triggering the activation of antigen-presenting cells (APCs) resident in solid tumors and their draining lymph nodes. Once activated, APCs recruit T cells into the vicinity of the tumor to deliver a potent anti-tumor immune response. Akamis has evaluated NG-350A's safety, tolerability, and preliminary efficacy as a monotherapy (FORTITUDE study) and in combination with pembrolizumab (FORTIFY study) in patients with metastatic or advanced epithelial tumors. Across these studies, NG-350A has demonstrated a consistent safety and tolerability profile, as well as strong evidence of tumor-selective delivery, replication and transgene expression.

NG-350A is currently being evaluated in the Phase Ib FORTRESS clinical study (NCT06459869) in combination with chemoradiotherapy (CRT) in adult patients with mismatch repair-proficient (pMMR) locally advanced rectal cancer (LARC) and at least one risk factor for local or distant recurrence or with oligometastatic disease.

ABOUT XUANZHU BIOPHARM

Xuanzhu Biopharm is the innovative drug subsidiary of Sihuan Pharmaceutical. It is an innovative pharmaceutical company with roots in China and a global perspective, focusing on major diseases such as digestion, oncology and non-alcoholic steatohepatitis, and is committed to the research and development, production and commercialization of class 1 drugs with core proprietary intellectual property rights. The company has a first-class R&D team, all core personnel have years of experience in new drug research and development. The company has two R&D platforms: small molecule chemistry and large molecule biologics. The dual engines drive the company's innovation and development, forming a product pipeline that covers small molecule chemistry, large molecule biopharmaceuticals, antibody-drug conjugate (ADC) and other types of products. With a focus on unmet major clinical needs, the company is committed to developing into a first-class innovative pharmaceutical company with independent research and development, production, and sales capabilities.

ABOUT SIHUAN PHARMACEUTICAL

Founded in 2001 and listed on the Main Board of The Stock Exchange of Hong Kong Limited in 2010, Sihuan Pharmaceutical is an international medical aesthetic and pharmaceutical company led by innovation, with an independent and leading research and development technology platform, a rich global product pipeline, strong product registration capability, a full dosage form production platform with high efficiency and low cost and a mature and excellent sales system. Adhering to the overall strategic goal for the "full promotion of a two-wheel drive strategy of its medical aesthetics and biopharmaceutical businesses", Sihuan Pharmaceutical endeavors to build itself into a leading medical aesthetics and biopharmaceutical company in China.

This announcement is being made by the Company on a voluntary basis to update the investing public on the Group's latest business development, and does not constitute, and is not intended to be, an advertisement regarding the use of any medicine, surgical appliance, treatment or orally consumed product.

By order of the Board
Sihuan Pharmaceutical Holdings Group Ltd.
Dr. Che Fengsheng
Chairman and Executive Director

Hong Kong, 28 October 2025

As at the date of this announcement, the executive directors of the Company are Dr. Che Fengsheng (Chairman), Dr. Guo Weicheng (Deputy Chairman and Chief Executive Officer), Dr. Zhang Jionglong, Ms. Chen Yanling and Ms. Miao Guili; and the independent non-executive directors of the Company are Mr. Tsang Wah Kwong, Dr. Zhu Xun and Mr. Wang Guan.